

K090720

Cochlear Americas

510(k) Premarket Notification
Cochlear Baha BP100

510(k) Summary

JUN 17 2009

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided.

Submitted by:

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On behalf of:

Cochlear Bone Anchored Solutions AB
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Date Submission Prepared:

March 2009

Device Name:

<i>Trade or Proprietary Name:</i>	Cochlear Baha® BP100
<i>Common or Usual Name:</i>	Hearing Aid (Bone Conduction)
<i>Classification Status:</i>	Class II, 21 CFR §874.3300 Product Codes: LXB
<i>Panel:</i>	Ear Nose and Throat Specialty Panel

Predicate Devices

The predicate devices for the Baha BP100 sound processor are the three currently marketed sound processors in the family of processors available for use with the Baha® auditory osseointegrated implant; namely, the Baha Divino™ (510(k) K042017), Baha Intenso™ (510(k) K081606), and Baha Cordelle II (510(k) K080363). Bench testing shows that the gain/output of the Baha BP100 are comparable to those for the marketed Baha Divino sound processor, and the intended use and technological characteristics of the Baha BP100 are substantially equivalent to the other three marketed sound processors. See Table 2 under Section XI of this submission for a detailed comparison of technological characteristics and features across the Baha family of sound processors used with the auditory osseointegrated implant.

Unique to the new Baha BP100 sound processor is that it can be programmed with fitting software, as well as manually adjusted like the predicate devices. The programming software and interface (described in Section XV of this submission) is substantially equivalent to other programming software that has been used for fitting of hearing devices that have digital signal processing algorithms. The fitting software, used on a standard computer, interfaces with the sound processor via cables to a standard HI-PRO box or NOAH-link, and has the same intended use and works in the same manner as that of many programmable hearing aids and devices. Predicate devices proposed for the fitting software system are 510(k) number K973880 for the Sonix hearing aid fitting and programming system, 510(k) number K931372 for the Resound® portable prescriptive programming system, and 510(k) number K942749 for the HI-PRO/NOAH universal hearing instrument by Madsen Electronics.

Also unique to this new Baha sound processor is the ability to measure bone-conduction thresholds directly via pure tones generated by the sound processor. The intended use and process to accomplish these measurements is also substantially equivalent to a procedure used by a previous hearing device cleared for marketing under the 510(k) process. Specifically, the predicate for obtaining data to assist in more accurate fittings by obtaining measurements for pure tones produced by the hearing device can be found in 510(k) number K984547 for the LGOB test using the Resound® digital 5000 series hearing devices. Although that approach uses suprathreshold measures to determine perceived loudness and the BP100 direct bone conduction measurements use threshold-level stimuli, the production of pure tones through the hearing device for standard audiometric measurements to be used in a prescription has the same intended use, function, and technology as the predicate.

Device Description

The Baha implant system works by combining a sound processor with an abutment and a small titanium implant placed in the skull behind the ear. The system is based on the process of “osseointegration” through which living tissue integrates with titanium in the

implant. Thus, the titanium implant becomes one with the bone, allowing high-quality amplified and processed sound to be conducted via the skull bone directly to a cochlea with residual functionality. Baha sound processors can also be fitted as external (non-implanted) bone-conduction vibrators with either the Baha Headband or Baha Softband as an alternative to a conventional bone-conduction hearing aid.

The Baha BP100 will be the newest addition to a current family of three marketed sound processors for use with the Baha auditory osseointegrated implant, or with the Baha Headband/Softband setup. In its initial release, it will provide a moderate gain ear-level sound processor that will serve as a premium-feature option to the currently marketed Baha Divino. At a later date, the BP100 platform may be used to provide a range of programmable products to meet end-user needs.

Intended Use

The Baha system is indicated for patients who have conductive or mixed hearing loss, and who can still benefit from sound amplification. Patients with bilaterally symmetric conductive or mixed hearing loss may be implanted bilaterally. The Baha system is also indicated for patients with sensorineural deafness in one ear and normal hearing in the other ear (i.e. single-sided deafness or “SSD”), and patients who are candidates for an air-conduction contralateral routing of signals (AC CROS) hearing aid but who for some reason cannot or will not wear an AC CROS device.

For the Baha implant, patients must be \geq 5 years old (per 510(k) K984162). They also must (either by themselves or with the aid of others) be able to maintain hygiene of the abutment/skin interface of the Baha. Finally, they should have sufficient bone volume and bone quality to support successful fixture placement. For patients not meeting these criteria for implantation, the Baha sound processor can be fit externally (non-implanted) with the Baha Headband or Baha Softband for transcutaneous bone-conduction stimulation.

The BP100 offers gain/output that is comparable to that supplied by the currently marked Baha Divino sound processor. Thus, it will be marketed for use for conductive or mixed hearing loss patients who have average bone-conduction thresholds up to ≤ 45 dB HL (across 0.5, 1, 2, and 3 kHz), the same Indications For Use as cleared for marketing of the Baha Divino.

Technological Characteristics

Baha BP100 is an external sound processor that utilizes digital signal processing with a number of advanced automatic features, for use with the Baha auditory osseointegrated implant, or with the Baha Headband/Softband. It has substantially equivalent technology, and intended use, as the other three currently marketed sound processors for the Baha system (Baha Divino, Baha Intenso, Baha Cordelle II). The external sound processors of the

Baha system differ in style, size, signal processing capability, features, and degree of available gain and output, but they are all interchangeable in that they all snap onto the abutment of the Baha auditory osseointegrated implant or are affixed to the skull using a Baha Headband/Softband.

Choice of Baha sound processor(s) depends on the individual needs and desires of a given patient. The Intenso is often chosen for patients who have greater gain needs than can be met with the Divino (i.e. those with mixed losses and poorer bone-conduction hearing thresholds), but who want the cosmetic discretion of wearing an ear-level device rather than the bulkier (body-worn) but most powerful Cordelle II. The BP100 will offer a “premium” alternative to the Baha Divino because it offers more advanced signal processing and available features, and can be programmed either manually via button pushing or with software (while the previously marketed sound processors are only able to be manually adjusted). Specifically, Baha BP100 provides advanced capabilities including multi-band wide-dynamic range compression, automatic background noise management, automatic directionality, and active feedback cancellation. Three user-selectable programs are available to customize the amplification for different environments such as listening in quiet, in noise, or to music (or, alternately, one program can be dedicated to accessory use via the DAI input port). It also will provide a new design with high cosmetic appeal, and a number of other features to meet end-user needs, such as FM unit and telecoil compatibility, direct audio input via an adaptor, tamperproofing functions for children, and usage data-logging. Use of the (recommended, but optional) software fitting capability will provide greater fitting accuracy, especially for difficult-to-fit patients.

Non-Clinical Tests

Although Cochlear is not declaring conformity to these standards, note that the following standards (or relevant elements of these standards) were used as guidelines in the manufacturing and development process for the Baha BP100 implant:

- ISO 13485 (Medical devices. Quality management systems. Requirements for regulatory purposes)
- ISO 60601-1 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)
- ISO 11137-1 (Sterilization health care products. Requirements for validation and routine control. Radiation sterilization)
- ISO 14971 (Medical devices. Application of risk management to medical devices)
- ISO 5832-2 (Implants for surgery – Metallic materials. Part 2: Unalloyed titanium)
- ISO 10993-1 (Biological evaluation of medical devices. Part 1: Evaluation and testing)
- ISO 17664 (Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices)

- EN 10088-1 (Stainless steels. List of stainless steels)
- EN 552 (Sterilization of medical devices. Validation and routine control of sterilization by irradiation)
- EN 556-1 (Sterilization of medical devices. Requirements for medical devices to be designated “sterile”. Requirements for terminally sterilized medical devices)
- EN 868-1 (Packaging materials and systems for medical devices which are to be sterilized. Part 1: General requirements and tests methods, and Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction. Requirements and tests methods)
- EN1174-1 (Sterilization of medical devices. Estimation of the population of micro-organisms on product. Requirements)
- EN 980 (Graphic symbols for use in the labeling of medical devices)
- EN 1041 (Information supplied by the manufacturer with medical devices)
- ASTM F67-06 (Standard specification for unalloyed titanium for surgical implant applications).
- IEC 60118-7 (Hearing aids: measurements of performance characteristics of hearing aids for quality inspection for delivery purposes)
- IEC 60188-9 (Hearing aids: methods of measurements of characteristics of hearing aids with bone vibrator output)
- ANSI S3.22 (Specification of hearing aid characteristics)

Clinical Performance Data

Published data in the literature support the safety and efficacy of the Baha Divino for patients with average bone-conduction thresholds of ≤ 45 dB HL (e.g. Kompis *et al.*, 2007). Because bench testing shows that the Baha BP100 is essentially equivalent (or better) than the Baha Divino in terms of gain/output, we believe that further clinical performance data are unnecessary to prove that the BP100 can successfully fit the same patient population; i.e. those with bone-conduction thresholds averaged across 500, 1000, 2000, and 3000 Hz of ≤ 45 dB HL.

Conclusions

The design and function of the Baha BP100 are substantially equivalent to previous Baha[®] sound processors cleared by the 510(k) process. The optional software fitting system for the Baha BP100 is substantially equivalent to that routinely used to fit conventional air-conduction hearing aids that use digital signal processing, including direct bone conduction (DBC) measurements, and the manual fitting approach for the BP100 is substantially equivalent to that used with currently marketed Baha sound processors. In addition, testing of the Baha BP100, including inspectional, functional and environmental tests, verify that the device meets key requirements in the design specification. Bench testing supports the proposed Indications For Use, since gain/output are equivalent to the Baha Divino which is currently marketed under 510(k) K042017 for the same Indications For Use.

Reference:

Kompis, M, Krebs, M, Hausler, R. (2007). *Speech understanding in quiet and in noise with the bone-anchored hearing aids Baha Compact and Baha Divino.* Acta Otolaryngol; 127(8): 829-835.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2009

Cochlear Americas
c/o Mr. Sean Bundy
Manager, Regulatory Affairs
13059 East Peakview Ave.
Centennial, CO 80111

Re: K090720

Trade/Device Name: Cochlear Baha® BP 100
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: May 20, 2009
Received: May 21, 2009

Dear Mr. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090720

Indications for Use

510(k) Number (if known): K090720

Device Name: Cochlear Baha® BP100

Indications for Use Statement:

The Cochlear Baha BP100 sound processor is intended for use with the Baha auditory osseointegrated implant (for children aged 5 and older, or adults), or with the Baha Headband or Baha Softband (no age limitations), for the following patients and indications:

- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL.
- Bilateral fitting of the BP100 is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies.
- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. single-sided deafness or "SSD"). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL.
- Baha for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

Prescription Use X
(21 CFR 801 Subpart C)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen Baker

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K090720